Panel Questions

Ophthalmic Devices Panel

July 14, 2006

1. Please discuss the following regarding endothelial cell density:

    a. The primary safety endpoint for this study was mean ECD ≤ 17%. The sponsor reported mean percentage change in ECD from baseline to 12 months of 25.3%. Does the panel believe that the study design has provided sufficient data to address the long-term ECD safety issue associated with this device?

    b. Please discuss whether these data provide a reasonable assurance of the safety of the IMT for the proposed indicated population. Please comment on whether any safety concerns regarding loss of ECD can be mitigated by limiting the intended population based on the following:

        - anterior chamber depth
        - minimum preoperative endothelial cell density at entry
        - age
        - other

2. With regard to the long-term follow-up of eyes with the IMT:

    a. Performing YAG capsulotomy through the center of the IMT can damage the lenses. The sponsor has proposed needling or a new method for performing capsulotomy through the periphery of the telescope. Please discuss whether such management of posterior capsular opacification provides a reasonable assurance of safety for patients with the IMT.

    b. Please discuss your concerns, if any, regarding posterior segment examination and treatment of eyes with the IMT.

3. The proposed safety and effectiveness criteria for visual acuity are based on unadjusted preoperative acuity rather than on acuity predicted from the magnified postoperative retinal image.

    a. Please discuss whether the unadjusted preoperative acuity baseline is adequate for evaluation of safety and efficacy of this device.

    b. Please provide any recommendations on what additional analyses are needed, if any, to evaluate visual acuity measures of safety and effectiveness.

4. In the IMT trial, the rehabilitation program was implemented by the subject with assistance from the family. Professional orientation and mobility and reading instruction were not provided. No validated methods of measuring the outcomes of training were utilized in this study.

    a. Please discuss whether you believe that the functional safety and effectiveness of the IMT has been adequately addressed with the vision rehabilitation program and the quality of life questionnaires used in this study.

    b. If not, please discuss modifications to the vision rehabilitation program recommended for patients that receive the IMT.

5. Regarding the rehabilitation training program to teach IMT subjects to use their implanted eyes for central vision tasks and their fellow eyes for peripheral vision tasks:

    a. The sponsor has provided no direct performance measures showing that subjects can learn to shift binocular suppression from one eye to the other at will. Please discuss whether the available evidence provides reasonable assurance that IMT subjects can safely and effectively use their IMT eye for central vision and their fellow eye for peripheral vision.

    b. Please provide any recommendations you may have for modifying the instructions for dealing with binocular rivalry and suppression problems.

6. The sponsor proposed the following indication for the IMT:

    The IMT implant is indicated for use in adult patients with bilateral, stable moderate to profound central vision impairment due to macular degeneration. Patients selected for implantation should meet the following criteria:

    - 55 years of age or older with bilateral, stable central vision disorders resulting from age-related macular degeneration as determined by fluorescein angiography, and evidence of cataract.

    - Distance BCVA between 20/80 and 20/800, and adequate peripheral vision in one eye (the non-targeted eye) to allow for orientation and mobility.

    - Achieve at least a five-letter improvement on the ETDRS chart in the eye scheduled for surgery using an external telescope.

    - Show interest in participating in a postoperative visual rehabilitation program.

Please discuss whether you believe that the data presented in the PMA support reasonable assurance of safety and efficacy of the IMT for the proposed indication. If not, please comment on whether your concerns can be mitigated by modifying the following:

a. Age

b. Preoperative VA

c. Definition of minimal acceptable peripheral vision

d. Type of AMD

e. other